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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,106	07/26/2007	Karl-Heinz Kogel	12810-00067-US	9243

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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,106	KOGEL ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 12/15/09 in reply to the Office action of 09/15/09 has been entered. Claims 1-3, 7-9, 12, 14, 17, and 20 are amended. The CRF of 01/06/10 has been entered.

Claims 1-23 are pending.

Claims 1-23, drawn to sense/antisense dsRNA of a DNA encoding SEQ ID NO: 2 or the nucleic acid of SEQ ID NO: 1 are examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

Claim Objections

Claims 2-3 and 12-13 remain objected to for reciting non-elected sequences and claims 4-5 and 21 recite a non-elected invention. In the response of 12/15/09, Applicant argues that according to the restriction requirement of 05/28/09, the restriction between the sequences and between the different methods of reducing NADPH oxidase activity was subject to the non-allowance of the generic claims. This is not found persuasive because no generic claim is deemed allowable. Therefore, the restriction requirement still applies.

Claim Rejections - 35 USC § 112

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dsRNA comprising the nucleic acid sequence of

SEQ ID NO: 1; an expression cassette comprising said dsRNA sequences, and a method of generating or increasing at least one pathogen resistance in a plant/cell/part/or progeny thereof using dsRNA nucleic acid sequences, and transgenic plants comprising said nucleic acid sequences, does not reasonably provide enablement for any method of reducing NADPH oxidase content/activity/function and using other than NADP oxidase nucleic acids or using sequences having 50% homology, or sequences which are identical or complementary to a part of SEQ ID NO: 1 or to a part of a nucleic acid encoding SEQ ID NO:2 or a dsRNA comprising a sense or antisense strand of a nucleic acid encoding a NADPH oxidase for inhibition of NADPH oxidase protein, and a transgenic animal comprising said dsRNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 09/15/09. Applicant's arguments filed 12/15/09 have been considered but are not deemed persuasive.

Applicant argues that the specification provides working examples that show the full-length dsRNA comprising sense and antisense sequences of SEQ ID NO: 1 which inhibited NADPH oxidase activity in transgenic plants. Applicant also argues that the specification provides guidance for how to clone cDNA encoding a NAPDH oxidase and how to synthesize in vitro dsRNA of a NAPDH oxidase to transiently transform dsRNA into a plant cell to induce RNA interference as well as methods of evaluating pathogen resistance in the transformed plant cells. Applicant asserts that the working examples

provided in the specification would enable one of skill in the art to obtain and use any other sequences encoding NAPDH oxidase to reduce protein quantity, activity or function of an endogenous NADPH oxidase encoding sequence using the different methods disclosed in the specification. Applicant contends that all the methods for obtaining and using NADPH sense, antisense, or dsRNA to produce transgenic plants and testing the transgenic plants for pathogen resistance would not require undue experimentation, given the guidance in the specification and the knowledge of one of ordinary skill in the art. Applicant also argues that the specification provides knock-out Arabidopsis plants were generated using the sequence of SEQ 1D NO: 11 by a different method in inhibiting the quantity, activity or function of the encoded NAPDH oxidase. Applicant points to Examples 2-5 of the specification in to support these arguments.

These are not found persuasive because Applicant's arguments are not commensurate in scope with the claims. The specification does not provide guidance for the broad scope of the methods of reducing NADPH oxidase content/activity/function in any organism and the broad scope of products required to reduce NADPH oxidase content/activity/function in any organism. The breadth of the claim encompasses different methods of reducing protein quantity, function or activity of an NADPH oxidase in a plant or tissue, organ, part or cell thereof, wherein the NADPH oxidase includes a functional equivalent of the SEQ ID NO: 2 or has at least 50% sequence identity thereto. The claims require any product that can be used to reduce an NADPH oxidase protein quantity, function or activity in a plant using any method. Therefore, the products

required for the claimed method and transgenic plants are not limited to NADPH oxidase nucleic acids.

In contrast, the specification provides guidance for a plant transformation method using dsRNA comprising full length SEQ ID NO: 1. While the specification mentions that an antisense or sense suppression of SEQ ID NO: 1 can also be used to reduce NADPH oxidase expression, the state of the prior art as evidenced by Schiene et al (Mol Gen Genet (2000) 263:761-770) provides unpredictability inherent in using either sense or antisense technology to reduce endogenous gene expression. Schiene et al teach transformation of tobacco plants with an antisense construct from Alfalfa failed to produce the expected disease resistant in tobacco plants (see Tables 1-3 and pages 765-767). In addition, since NADPH oxidase are encoded by a multigene family, one of ordinary skill in the art would not expect that using an antisense or sense suppression methology would inhibit or reduce NADPH oxidase activity in the plant. Applicant has provided no evidence to the contrary. See also, In Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999), where the court held the claims in two patents directed to genetic antisense technology (which aims to control gene expression in a particular organism), were invalid because the breadth of enablement was not commensurate in scope with the claims. The court relied on the fact that (1) the amount of direction presented and the number of working examples provided in the specification were very narrow compared to the wide breadth of the claims at issue, (2) antisense gene technology was highly unpredictable, and (3) the amount of experimentation required to adapt the practice of creating antisense DNA from E. coli to

other types of cells was quite high. Therefore, the specification does not disclose a representative number of products that can be used to reduce NADPH oxidase content/activity/function in plants and hence induce pathogen resistance in the plants.

While Applicant is not required to exemplify each and every claimed embodiment, the 35USC 112, 1st paragraph requires that the breadth of the claims be commensurate with the enabling disclosure. See MPEP 2164. The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation'." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). See also in re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where the court held that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims.

Regarding Applicant's arguments that the specification discloses different methods and products for the claimed methods and plants, it is noted that the disclosed products and methods are not representative sample and the scope of the claims is not supported by an enabling disclosure. In Genentech Inc v. Novo Nordisk A/S (42 USPQ2d 1001 at p. 1005) the court stated "(p)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimidations of general ideas that may or may not workable ..... When there is no disclosure of ....or of any of the conditions under which a process can be carried out, undue experimentation is required.

Regarding the attached figure showing knockout Arabidopsis plants using SEQ ID NO: 11 and a different method, it is noted that the evidence should have been submitted in the form of 132 declarations and showing of the steps, materials, and conditions used in the experiments of the declaration.

Therefore, given the lack of guidance in the specification and in the prior art; the scope of the claims encompassing the use of any product other than NADPH sequences or parts thereof to inhibit or reduce activity/function/amount of NADPH oxidase in any organism including animals; the unpredictability inherent in using antisense or sense constructs to induce defense response in as evidence by Schiene et al above, and the nature of the invention, as discussed above and in the last Office action, the claimed invention cannot be practiced throughout the broad scope without undue experimentation , therefore, the invention is not enabled.

Claim Rejections - 35 USC § 112

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 09/15/09. Applicant's arguments filed 12/15/09 have been considered but are not deemed persuasive.

Applicant argues that the specification describes SEQ ID NO: 1 and a method of transforming dsRNA comprising SEQ ID NO: 1 to generate plants having increased

pathogen resistance as shown in Examples 2-4. Applicant also argues that the specification discloses a representative number of NADPH oxidases including SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, or 22 and GenBank accession number of additional NAPDH oxidases. Applicant cites University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997) to support this position (response, pp. 15-16) .

These are not found persuasive because the claimed methods of reducing NADPH oxidase content/activity/function are not limited to the use of NADPH oxidase sequences. The claimed method requires any product that is capable of reducing an amount/activity/function of a NADPH oxidase in an organism including a plant or animal. The composition and structure of such products other than NADPH oxidase capable of reducing an amount/activity/function of a NADPH oxidase in an organism including a plant or animal are unknown. Only full length NADPH nucleic acids are described in the specification as capable of reducing endogenous NADPH oxidase content/activity/function in a plant. Therefore, Applicant has not described a representative number of products capable of reducing amount/function/activity of a NADPH oxidase in any organism.

Therefore, for all the reasons discussed above and in the last Office action, the claimed invention does not meet the current written description requirements.

Remarks

No claim is allowed.

The claims are deemed free of the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
3/25/2010

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638